

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte XINGWU WANG, CHAONAN CHEN,
and HUIHUI DUAN

Appeal 2007-4237
Application 10/035,985
Technology Center 1700

Decided: October 31, 2007

Before BRADLEY R. GARRIS, CHUNG K. PAK, and
CHARLES F. WARREN, *Administrative Patent Judges*.

PAK, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1 through 3 and 6 through 18, all of the claims pending in the above-identified application. We have jurisdiction pursuant to 35 U.S.C. § 6.

STATEMENT OF THE CASE

The subject matter on appeal is directed to an implantable biochemical fuel cell which is said to use body fat to produce electricity (Spec. 1). Further details of the appealed subject matter are recited in representative claim 1 reproduced below:

1. An implantable fuel cell assembly comprised of means for converting fat to glycerol and fatty acid, means for converting glycerol to hydrogen, means for converting fatty acid to hydrogen, means for converting a bodily fluid to a gas selected from the group consisting of hydrogen, oxygen, and mixtures thereof, and fuel cell means for producing electricity from hydrogen and oxygen.

At pages 7 through 14, the Specification defines the structures and materials corresponding to the means limitations recited in claim 1 as follows:

[T]he dislodged fat cells that pass through wall 12 are contacted with one or more lipase enzymes 46. As is known to those skilled in the art, lipase enzymes catalyze the hydrolysis of fats to glycerol and fatty acids. These enzymes are well known to those skilled in the art ... In general, the lipase enzyme particles are preferably contiguous with the inner surface 48 of wall 12 but preferably are sufficiently spaced from each other so that the fat particles and/or the glycerol and/or fatty acids pass in the direction of arrow 50 . . .

. . .

Referring again to Figure 1, and in the preferred embodiment depicted therein, the glycerol material 52 and the fatty acid material 54 pass conversion chamber 58, in which the fatty acid(s) are converted to hydrogen and carbon dioxide. Disposed within the conversion chamber 58 are enzymes 60, 62, 64, and 66 which promote the beta oxidation of fatty acids and other reactions. As is known to those skilled in the art, beta

oxidation is the oxidation of fatty acids through successive cycles of reactions, with each operation of the cycle leading to a shortening of the fatty acid by a two-carbon fragment that is removed in the form of acetyl coenzyme A. Reference may be had, e.g., to United States patents 6,245,317, 6,160,138, 6,121,299,

.....

In addition to the beta-oxidase enzymes, one may utilize other enzymes in the system. One may feed the glycerol formed within chamber 48 to the living organism via port 70. Alternatively, one may feed such glycerol to a glycerol fuel cell (not shown) via port 72.

In one embodiment, the glycerol fuel cell utilized is described and claimed in United States patent 4,294,891 of ShangJ. Yao, the entire disclosure of which is hereby incorporated by reference into this specification. This patent describes a biologically acceptable, implantable, bio-oxidant fuel cell comprising in operative combination: (a) at least one anode assembly; (b) at least one cathode assembly; (c) a fuel/electrolyte chamber defined between said anode and said cathode assemblies for receiving an externally supplied fuel; (d) an electrical lead attached to each of said anode and cathode assembly to provide electrical output to a prosthesis; (e) a biologically acceptable, oxygen permeable membrane disposed substantially in contact with said cathode assembly so that said membrane lies between said cathode and body tissue, said membrane being adapted to permit endogenous tissue O₂ as a biological oxidant to diffuse into said cell from said body tissue; a (f) [sic. (f) a] fuel/electrolyte composition disposed in said fuel/electrolyte chamber; and (g) said fuel/electrolyte composition having a high concentration ratio of fuel to endogenous tissue O₂ diffusing through a device.

...

In one embodiment, hydrogen peroxide present within a patient's bodily fluid(s) is converted to water and oxygen. As will be apparent, in addition to providing oxygen for the fuel

cell 112, this embodiment also reduces the level of harmful oxidizing agent within the body.

United States patents 4,294,891 discloses an assembly coated with a medical grade silicone rubber such as, e.g., medical adhesive silicone type A silicone elastomer "SILASTIC" brand made by Dow Coming, or an RTV of silicone rubber made by General Electric Corporation. Any coating material which is biocompatible, nonreactive, tissue acceptable, and permitting oxygen diffusivity therethrough may be used in the device of such patent; such material must prevent the diffusion outwardly from the electrolyte chambers of such patent of either the electrolyte/fuel solution or any toxic oxidation/reduction product.

As evidence of unpatentability of the claimed subject matter, the Examiner has relied upon the following references:

Voet et al. (Voet), *Lipid Metabolism*, Biochemistry, John Wiley & Sons, 618-621 (1990).

The Examiner has rejected claims 1 through 3 and 6 through 18 under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the [claimed] invention..."

The Appellants appeal from the Examiner's decision rejecting the claims on appeal under 35 U.S.C. § 112, first paragraph, as lacking an enabling disclosure for the claimed subject matter.

PRINCIPLES OF LAW, FACTS, ISSUES and ANALYSES

The Specification is presumed to be "in compliance with the enabling requirement of 35 U.S.C. § 112, first paragraph, unless there is reason to

doubt the objective truth of the statements contained therein.” *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). The Examiner has the initial “burden of giving reasons, supported by the record as a whole, why the [S]pecification is not enabling.....Showing that the disclosure entails undue experimentation is part of the PTO’s initial burden....” *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976). In determining whether any given disclosure would require undue experimentation to make the claimed invention, the Examiner must consider “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Some experimentation, even a considerable amount, is not “undue” if it is merely routine, or if the Specification provides a reasonable amount of guidance as to the direction of the experimentation. *Wands*, 858 F.2d at 737.

The Examiner’s rejection of all of the appealed claims under 35 U.S.C. § 112, first paragraph, as lacking adequate enabling support is apparently predicated upon the Examiner’s doubt that the claimed implantable fuel cell assembly is operative (Ans. 4-8).¹ Specifically, the Examiner contends (Ans. 4) that:

It is unclear how the lipase enzymes can effectively be

¹ See *In re Fouche*, 439 F.2d 1237, 1242 (CCPA 1971) (In situations where the operativeness of a claimed invention is challenged, the Examiner may properly impose a rejection under 35 U.S.C. § 101 for lack of utility and/or under the first paragraph of 35 U.S.C. § 112, for lack of adequate enabling support as to how to use the claimed invention).

replenished and/or regenerated to retain the conversion process. The disclosure does not discuss or suggest the source of the lipase enzymes and how the degradation of the enzymes might affect the process. Moreover, fatty acids is [sic., are] known to form micelles that act as detergents to disrupt protein and membrane structure and would therefore be toxic to humans if the concentration is higher than 10^{-6} M. See "Biochemistry" by D. Voet and J. Voet, p. 621. The disclosure does not elaborate or even mention the potential catastrophic events to the recipient of such implant. This raises doubts about the feasibility and practicality for the use of fatty acid as an intermediate product in the production of hydrogen fuel. More importantly, it is know [sic., known] in the art that glycerol can be broken down to become dihydroxyacetone phosphate and hydrogen proton (H^+) as shown in the reaction ... "Biochemistry" by D. Voet and J. Voet, p. 620.....In contrary, the instant disclosure teaches the use of molecular hydrogen (H_2) as fuel to produce electricity as recited in claim 1 and Figure 1.

In other words, the Examiner believes that the features "means for converting fat to glycerol and fatty acid" and "means for converting glycerol to hydrogen" recited in claim 1 are inoperative. These features, consistent with the Specification discussed *supra*, are interpreted as the porous chamber containing lipase enzymes described in the Specification or equivalents thereof and the porous chamber containing beta-oxidase enzymes described in the Specification or equivalents thereof, respectively. *In re Donaldson*, 16 F.3d 1189, 1193 (Fed. Cir. 1994)(*in banc*).

The dispositive question is, therefore, whether the Examiner has demonstrated that the porous chambers containing lipase enzymes and beta-oxidase enzymes are incapable of performing the functions described in the

Specification, without undue experimentation, within the meaning of 35 U.S.C. § 112, first paragraph? On this record, we answer this question in the negative.

As to the chamber containing lipase enzymes, the Examiner has not questioned the Specification's statement that the lipase enzymes are known and are capable of converting fats into glycerol and fatty acids. The Examiner's reference to the importance of replenishing and/or regenerating lipase enzymes for a prolonged use does not demonstrate that the claimed implantable fuel cell assembly is inoperative. It is significant to note that the enablement requirement under § 112 does not mandate that the Specification "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003).

As to the chamber containing beta-oxidase enzymes, the Specification indicates that it is used to convert fatty acids and glycerol into, *inter alia*, hydrogen. The Examiner has not demonstrated that it does not convert glycerol into, *inter alia*, hydrogen as claimed. The Examiner's own evidence (Voet) shows that glycerol is used to produce, *inter alia*, protonated hydrogen which is encompassed by the claimed hydrogen. In addition, Yao relied on by the Specification as discussed *supra* also shows at col. 4, ll. 40-55, that glycerol can produce protonated hydrogen and donate electrons simultaneously, which, according to the Examiner at page 8 of the Answer, would produce hydrogen gas.

Even were we to assume that the Specification itself does not provide sufficient details to render the claimed implantable fuel cell assembly operative, the Examiner's analysis should not end at that point. Applying

the factors enumerated in *Wands* to the present facts, the Examiner must determine whether undue experimentation is needed to render the chambers containing lipase and beta-oxidase enzymes of the claimed implantable fuel cell assembly operative. However, as is apparent from the Answer, the Examiner's analysis does not take into account, *inter alia*, the level of one of ordinary skill in the art, the nature of the invention and the state of the prior art in determining whether undue experimentation is needed to make and use the claimed implantable fuel cell assembly as required by *Wands*.

Accordingly, we are constrained to agree with the Appellants that the Examiner, on this record, has not demonstrated that undue experimentation is needed to make and use the claimed implantable fuel cell assembly within the meaning of the first paragraph of 35 U.S.C. § 112.

ORDER

In view of the forgoing, the decision of the Examiner is reversed.

REVERSED

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sld/lis

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